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Product Code	Product Name	UDI-DI
PN186	0.5 IU/mL anti-D control	05055232400468

Amendments from the previous version of these instructions for use are in purple text.

Intended Use

For professional use as an IVD device for the control of automated blood grouping and antibody screening systems. This reagent can be used to give qualitative data to assure the effectiveness of each batch of laboratory tests. The device is intended for QC of the automated system as a whole and not as a specific control for blood grouping. This reagent is not suitable for use as an anti-D grouping reagent.

Principles of the examination method

Reagent is incubated with red blood cells known to exhibit the appropriate antigen in an automated test system to show that the system, at that time, can detect an antibody/antigen reaction when testing unknown samples by immunohaematological methods.

Components

This reagent is prepared from human sera/plasma containing anti-D.
This reagent has been prepared using a diluent containing 30 g/L bovine serum albumin from a BSE free source, sodium azide as a bacteriostat at less than 0.1% and PBSS.
It is supplied in 10 mL volume, to be used directly from the vial.

Special materials and equipment required but not supplied

This reagent is supplied to be used in automated testing only

Reagent preparation

Allow to reach required temperature for the test to be performed.
Use reagent as supplied.

Storage and shelf life after opening

Store at 2-8ºC.
Once opened the device can be used until the stated expiry date.
Do not use beyond the expiry date.
Protect from contamination.
Immediately after use, the vial must be capped and placed, upright, in the correct storage temperature.

Warnings and precautions

The donations used in this product are of human origin. They have been tested and found negative for the mandatory microbiological tests required by the UK Guidelines for Blood Transfusion Services during donation testing. No known test methods can offer assurances that products derived from human blood will not transmit infectious diseases. This device

should be handled as clinical material. The device and any contaminated packaging should be disposed in accordance with local, state, or national legislation.
For healthcare professional use only.
This reagent has not been absorbed to remove ABO alloagglutinins. The reagent may contain weak anti-C and/or E which maybe active in systems using enzyme treated cells.
The recommended conditions of storage and use must be rigidly applied.
The reagent should not be used if cloudy or opaque.
If a precipitate, gel or particles are present the reagent should be centrifuged before use.
When used in accordance with the Instructions for Use and Good Laboratory Practices, there is limited potential for carryover.
This device is not provided sterile.
Do not use if the reagent vial is cracked or leaking.

Examination procedure
For method of use refer to the instructions for use of the automated equipment being used.

Interpretation of results
The presence of agglutination indicates a positive result. 0.5 IU/mL anti-D control must give an unequivocal positive result. The strength of reaction should be graded in accordance with automated equipment being used. Failure to obtain an unequivocal positive reaction must be investigated and any associated batch of tests repeated.

Performance characteristics
The absence of other blood group antibodies has been assured using a panel of red cells which bear the following antigens: C, D, E, c, e, Le^a, Le^b, K, Kp^a, P_1, C^w, M, N, S, s, Lu^a, Jk^a, Jk^b, Fy^a, Fy^b.
Negative reactions with this panel also exclude the presence of antibodies to antigens having a prevalence of greater than 99%.
Antibodies to low incidence blood group antigens may occur as contaminants and may, on rare occasions, give rise to false positive results.
Group O RhD+ positive red cells which have been found to be direct antiglobulin test negative should be used with this reagent.

Limitations of the examination procedure
This reagent is not suitable for use as an anti-D grouping reagent.
If controls set up with the batch of tests fail to give the required results, then all tests must be repeated.
Suitability for use in other techniques must be validated by user.
The precise conditions for red cell suspension, ratio, incubation, and reading must be identical to those of the batch of tests being controlled.
False positive or false negative results may occur due to contamination of test material, improper storage, incubation time or temperature or improper or excessive centrifugation.

Literature references
Directive 98/79/EC on in vitro diagnostic medical devices.
Guidelines for the Blood Transfusion Services in the UK.

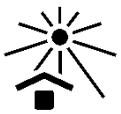
Note – Any serious incident that has occurred in relation to this 0.5 IU/mL anti-D should be reported to the manufacturer and the competent authority in which the user and/or the patient is established.

EC REP
Quality First International OÜ, Laki 30,12915 Tallinn, Estonia.

Symbols used on NHSBT Reagents labels

Note - not all symbols listed are applicable for this product - please refer to product labels.

Detail	Label details
Batch code symbol	LOT
Use by date symbol	
Expiry date format	YYYY.MM.DD
In Vitro Diagnostic medical device symbol	IVD
Instructions for use symbol (With website - electronic IFU)	 blood.co.uk/reagents
Negative control symbol	CONTROL –
Positive control symbol	CONTROL +
EC Rep symbol	EC REP

Detail	Label details
2-8°C temperature range symbol	
Below -20°C symbol	
CE Mark symbol	
UKCA symbol	UKCA
Manufacturer's symbol	
Keep Away from Sunlight symbol	
Contains human blood or plasma derivatives symbol	
Unique Device Identifier symbol	UDI

Lot number Format

NHBST Reagents product lot numbers are in the following format:

NAAA MXXX or RAAA MXXX

N Non-Red cell or R Red cell

AAA Product identifier from product code

M Reagent Manufacturing Unit - main batch = 3
And sub-batch identifier - 4, 5, 6 .... etc for sub batch

XXX Lot number